Section II. (Remarks)

Response to the Obviousness-Type Double Patenting Rejection

In the June 15, 2004 Office Action, the Examiner rejected claims 1-3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,139,746 (hereinafter "the '746 Patent").

Applicants respectfully traverse.

Amended claim 1, from which claims 2-3 depend, expressly requires:

> "1. A method of milk separation, comprising **separating milk by cross-flow membrane filtration** to recover at least one nutraceutical milk product therefrom, wherein said method does not include recirculation of any chromatography resins in cross-flow filter."

The instant specification as originally filed states on page 10 that "[t]he present invention uses cross-flow filtration to **physically separate** and isolate the above listed components of milk, based on their different molecular weights and surface chemistry, and thus avoiding introducing any unnatural chemical additives into the milk products."

In contrast, claim 1 of the '746 Patent, which is representative of claims 1-62 thereof, recites:

> 1. A process for purifying one or more target substances from a source liquid, said process comprising:
>
> contacting the source liquid with a chromatography resin;
>
> incubating the source liquid with the chromatography resin for a sufficient contact time to allow the resin to bind a desired fraction of one or more target substances,
>
> **recirculating the chromatography resin in a cross-flow filter** wherein the following steps are performed:

concentrating the chromatography resin and separating contaminants from the chromatography-resin-bound target substance by concentration and/or diafiltration;

eluting the target substance from the chromatography resin; and

separating the target substance from the chromatography resin by diafiltration;

recovering the target; and

optionally concentrating the target substance."

Such claim 1 of the '746 Patent discloses a process in which recirculation of a chromatography resin in a cross-flow filter is required for the separation of the target substance. Specifically, the source liquid must first be contacted with the chromatography resin to allow binding between the target substance and the chromatography resin, while the chromatography resin with the target substance bound thereto is subsequently recirculated in a cross-flow filter so as to be separated from the source liquid.

The binding of the target substance with the chromatography resin and the recirculation of the chromatography resin in the cross-flow filter are critical and essential for the separation of such target substance from the source liquid in the method specified by claim 1 of the '746 Patent.

In the June 15, 2004 Office Action, the Examiner asserted that "the lack of chromatography... steps is dependent on the degree of purity and is merely a matter of choice" (see page 2, last paragraph of the Office Action).

Applicants rigorously disagree.

Nothing in the '746 Patent teaches or suggests that milk separation can be achieved without the chromatography resins, or that the use of chromatography resins is merely a matter of choice.

On the contrary, the entire methodology disclosed by the '746 Patent centers around the usage of chromatography resins and recirculation of such chromatography resins in cross-flow filters. Specifically, the '746 Patent teaches that milk proteins can be "separated sequentially from whey

by use of a series of specific chromatography resins, each linked with ligands that bond targeted proteins" (see '746 Patent, column 16, lines 26-35), and the milk separation process disclosed by the '746 Patent operates on the basis that different milk proteins have different binding affinities to different chromatography resins, which can be separated by recirculation in cross-flow filters.

An ordinary person skilled in the art, upon reading the '746 Patent, would immediately appreciate that usage of such chromatography resins is a critical and essential element of the method disclosed by the '746 Patent.

Therefore, claims 1-3 of the present application are patentably distinguished over claims 1-62 of the '746 Patent, by expressly excluding recirculation of any chromatography resin in cross-flow filter.

Applicants hereby request the Examiner to reconsider, and upon reconsideration to withdraw, the obviousness-type double patenting rejection of claims 1-3 of the present application.

Response to the 102(e) and 103(a) Rejection

In the June 15, 2004 Office Action, the Examiner rejected claims 1-3 under either 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being unpatentable over Kopf U.S. Patent No. 6,139,746 (hereinafter "Kopf").

Specifically, the Examiner asserted that Kopf teaches a method for separating components of milk comprising filtering the milk using cross-flow filtration, and that claim 3 of the Kopf reference discloses a step of cross-flow membrane filtration that does not include chromatography.

Applicants respectfully disagree, for the following reasons.

Claim 1 of the present application (from which claims 2-3 depend) expressly requires:

> "1. A method of milk separation, comprising separating milk by cross-flow membrane filtration to **recover at least one nutraceutical milk product**

therefrom, wherein **said method does not include recirculation of any chromatography resins in cross-flow filter**:"

It is clear from the claim language that Applicants' claimed invention is a milk separation method that:

(1) recovers at least one nutraceutical milk product; and

(2) does not include recirculation of chromatography resins in cross-flow filter.

The exclusion of recirculation of any chromatography resins in cross-flow filter by claims 1-3 of the present application is not limited to only one or two steps in the claimed method, but applies to the entire claimed method, i.e., to each and every step contained therein.

However, claim 3 of the Kopf reference defines a purification method that comprises not only an initial clarification step which does not involve usage of chromatography resin, but also subsequent steps in which chromatograph resin is recirculated in a cross-flow filter (see claim 1, from which claim 3 depends).

Therefore, the overall purification method disclosed by claim 3 of the Kopf reference still requires recirculation of the chromatography resin in cross-flow filter and does not provide any derivative basis for a milk separation method that does not include recirculation of any chromatography resins in the cross-flow filter, as required by claims 1-3 of the present application.

Further, the initial clarification step disclosed by the Kopf reference is optional, which only functions to remove undesirable particulates or contaminants (see Kopf, column 4, lines 4-5; column 12, lines 41-44), and it does not separate the target substances from the source liquid.

On the other hand, nothing in Kopf teaches or suggests that recirculation of the chromatography resins in the cross-flow filters is optional, or that milk separation can be achieved without such chromatography resins.

Instead, Kopf teaches that milk proteins can be "separated sequentially from whey by use of a series of specific chromatography resins, each linked with ligands that bond targeted proteins"

(see Kopf, column 16, lines 26-35). An ordinary person skilled in the art, upon reading Kopf, would readily understand that usage of such chromatography resins is a critical and essential element of the method disclosed by Kopf.

Therefore, Applicants' claimed invention as recited by claims 1-3 of the present application patentably distinguishes over the Kopf reference, by requiring a milk separation method that does not include recirculation of any chromatography resins in cross-flow filter.

CONCLUSION

Based on the foregoing, pending claims 1-3 as amended herein are in form and condition for allowance. Favorable action therefore is requested.

No fee is rendered payable in association with this Amendment. Nevertheless, the Office is hereby authorized to charge any fee that is necessary for the entry of this Amendment to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

If any issues remain outstanding in this application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350.

Respectfully submitted,

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